

K123001

**510(k) Summary**  
**Prepared August 22, 2012**

OCT 26 2012

**Sponsor:** Siemens Medical Solutions, Inc.,  
Ultrasound Division  
685 East Middlefield Road  
Mountain View, California 94043

**Contact Person:** Shelly Pearce  
Telephone: (650) 694-5988  
Fax: (650) 694-5580

**Device Name:** ACUSON X700™ Ultrasound System

**Common Name:** Diagnostic Ultrasound System with Accessories

**Classification:**

Regulatory Class: II  
Review Category: Tier II  
Classification Panel: Radiology

Ultrasonic Pulsed Doppler Imaging System	FR # 892.1550	Product Code 90-IYN
Ultrasonic Pulsed Echo Imaging System	FR # 892.1560	Product Code 90-IYO
Diagnostic Ultrasound Transducer	FR # 892.1570	Product Code 90-ITX
Diagnostic Intravascular Catheter	FR # 870.1200	Product Code OBJ

**A. Legally Marketed Predicate Devices**

The Siemens ACUSON X700™ Ultrasound System is a multi-purpose diagnostic ultrasound system with accessories and proprietary software, and is substantially equivalent to our current product, the Siemens ACUSON X300 ultrasound system (K121699), ACUSON S2000 ultrasound system (K112596) and Ultrasonix SonixTABLET ultrasound scanner (K113663, K102997).

**B. Device Description:**

The Siemens ACUSON X700™ is a multi-purpose mobile, software controlled, diagnostic ultrasound system with an on-screen display for thermal and mechanical indices related to potential bio-effect mechanisms. Its function is to acquire harmonic ultrasound echo data and display it in B-Mode, M-Mode, Pulsed (PW) Doppler Mode, Continuous (CW) Doppler Mode, Color Doppler Mode, Color M mode, Tissue Doppler Image, Amplitude Doppler Mode, a combination of modes, or Harmonic Imaging and 3D Imaging, or Harmonic Imaging and 4D imaging on a Flat Panel Display.

**C. Intended Use**

The Siemens ACUSON X700™ ultrasound imaging system is intended for the following applications: Cardiac (Adult, Pediatric), Transesophageal (Cardiac), Intracardiac, Cerebrovascular, Peripheral Vessel, Abdominal, Renal, Fetal, Abdominal, Intra-operative,

Pediatric, Small Organ, Neonatal Cephalic, Adult Cephalic, Orthopedics, Musculo-skeletal Conventional, Musculo-skeletal Superficial, Pelvic, Obstetrical, Gynecological and Urological applications.

The system also provides for the measurement of anatomical structures and for analysis packages that provide information that is used for clinical diagnosis purposes.

The Arterial Health Package (AHP) software provides the physician with the capability to measure Intima Media Thickness and the option to reference normative tables that have been validated and published in peer-reviewed studies. The information is intended to provide the physician with an easily understood tool for communicating with patients regarding state of their cardiovascular system. This feature should be utilized according to the "ASE Consensus Statement; Use of Carotid Ultrasound to Identify Subclinical Vascular Disease and Evaluate Cardiovascular Disease Risk: A Consensus Statement from the American Association of Echocardiography; Carotid Intima-Media Thickness Task Force, Endorsed by the Society for Vascular Imaging".

The Acuson Acunav Ultrasound Catheter is intended for intra-cardiac and intra-luminal visualization of cardiac and great vessel anatomy and physiology, as well as visualization of other devices in the heart of adult and pediatric patients

#### **D. Substantial Equivalence**

The Acuson X700 is substantially equivalent to the Acuson X300, cleared via K121699, and Acuson S2000, cleared via K112596 and SonixTABLET ultrasound scanner cleared via K113663. All systems transmit ultrasonic energy into patients, then perform post processing of received echoes to generate onscreen display of anatomic structures and fluid flow within the body. All systems allow for specialized measurements of structures and flow, and calculations.

The submission device is substantially equivalent to the predicate with regard to both intended use and technological characteristics.

#### **E. A brief discussion of nonclinical tests submitted, referenced, or relied on in the 510(k) for a determination of substantial equivalence**

The device has been evaluated for acoustic output, biocompatibility, cleaning and disinfection effectiveness as well as thermal, electrical, electromagnetic and mechanical safety and has been found to conform with applicable medical device safety standards. The system complies with the following voluntary standards:

- UL 60601-1, Safety Requirements for Medical Equipment
- IEC 60601-2-37 Diagnostic Ultrasound Safety Standards
- CSA C22.2 No. 601-1, Safety Requirements for Medical Equipment
- AIUM/NEMA UD-3, Standard for Real Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment
- AIUM/NEMA UD-2, Acoustic Output Measurement Standard for Diagnostic Ultrasound
- 93/42/EEC Medical Devices Directive
- Safety and EMC Requirements for Medical Equipment
  - EN/IEC 60601-1
  - EN/IEC 60601-1-1
  - EN/IEC 60601-1-2

- EN/IEC 60601-1-4
- EN/IEC 60601-1-6
- EN/IEC 60601-2-18
- EN/IEC 60601-2-25
- IEC 1157 Declaration of Acoustic Power
- ISO 10993-1 Biocompatibility

Cleared patient contact materials, electrical and mechanical safety are unchanged.

**F. A summary discussion of the clinical tests submitted, referenced, or relied on for a determination of substantial equivalence.**

Since the X700 uses the same technology and principles as existing devices, clinical data is not required.

**G. Summary**

Intended uses and other key features are consistent with traditional clinical practice and FDA guidelines. The design and development process of the manufacturer conforms with 21 CFR 820 Quality System Regulation and ISO 13485:2003 quality system standards. The product is designed to conform with applicable medical device safety standards and compliance is verified through independent evaluation with ongoing factory surveillance. Diagnostic ultrasound has accumulated a long history of safe and effective performance. Therefore it is the opinion of Siemens Medical that the X700 is substantially equivalent with respect to safety and effectiveness to devices currently cleared for market.

The Acuson X700 is verified and validated according to the company's design control process.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20993

OCT 26 2012

Siemens Medical Solutions USA, Inc. – Ultrasound Group  
% Mr. Mark Job  
Responsible Third Party Official  
Regulatory Technology Services LLC  
1394 25<sup>th</sup> Street NW  
BUFFALO MN 55313

Re: K123001

Trade/Device Name: Acuson X700™ Diagnostic Ultrasound System  
Regulation Number: 21 CFR 892.1550  
Regulation Name: Ultrasonic pulsed doppler imaging system  
Regulatory Class: II  
Product Code: IYN, IYO, ITX, and OBJ  
Dated: September 26, 2012  
Received: September 27, 2012

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the Acuson X700™ Diagnostic Ultrasound System, as described in your premarket notification:

Transducer Model Number

4C1 Curved Array  
VF10-5 Linear Array  
VF12-4 Linear Array  
EC9-4w Convex Array  
6C2 Curved Array  
CW2  
CW5  
AcuNav 8F Intracardiac  
AcuNav 10F Intracardiac

V5Ms TEE  
4V1c Phased Array  
C7F2 Curved Array  
EV9F4 Curved Array  
SoundStar 10F  
SoundStar eco 10F

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

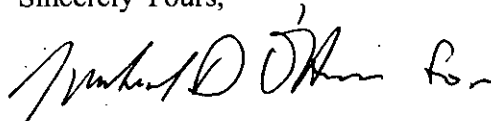
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOices/ucml115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

If you have any questions regarding the content of this letter, please contact Joshua Nipper at (301) 796-6524.

Sincerely Yours,



Janine M. Morris  
Director  
Division of Radiological Health  
Office of In Vitro Diagnostics  
and Radiological Health  
Center for Devices and Radiological Health

Enclosure(s)

## Tab 1.3.1 Indications for Use Forms

### Indications for Use Statement

510(k) Number (if known):

Device Name: ACUSON X700™ Diagnostic Ultrasound System

#### Indications For Use:

The Siemens ACUSON X700™ ultrasound imaging system is intended for the following applications: Cardiac (Adult, Pediatric), Transesophageal (Cardiac), Intracardiac, Cerebrovascular, Peripheral Vessel, Abdominal, Renal, Fetal, Abdominal, Intra-operative, Pediatric, Small Organ, Neonatal Cephalic, Adult Cephalic, Orthopedics, Musculo-skeletal Conventional, Musculo-skeletal Superficial, Pelvic, Obstetrical, Gynecological and Urological applications.

The system also provides for the measurement of anatomical structures and for analysis packages that provide information that is used for clinical diagnosis purposes.

The Arterial Health Package (AHP) software provides the physician with the capability to measure Intima Media Thickness and the option to reference normative tables that have been validated and published in peer-reviewed studies. The information is intended to provide the physician with an easily understood tool for communicating with patients regarding state of their cardiovascular system. This feature should be utilized according to the "ASE Consensus Statement; Use of Carotid Ultrasound to Identify Subclinical Vascular Disease and Evaluate Cardiovascular Disease Risk: A Consensus Statement from the American Association of Echocardiography; Carotid Intima-Media Thickness Task Force, Endorsed by the Society for Vascular Imaging".

The Acuson Acunav Ultrasound Catheter is intended for intra-cardiac and intra-luminal visualization of cardiac and great vessel anatomy and physiology, as well as visualization of other devices in the heart of adult and pediatric patients.

Prescription Use   X    
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

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\_\_\_\_\_  
Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

  
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Office of In Vitro Diagnostic Devices

510(k) K123001

Page 1 of \_\_\_\_\_

## Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name:  
Intended Use:

**ACUSON X700 Diagnostic Ultrasound Systems**

Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
Other (Track 1 Only)	Specific (Tracks 11 & 3)	B	M	PWD	CWD	Color Doppler	Power Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic								
Fetal  Imaging & Other	Fetal	P	P	P	P	P	P	BMDC	Note 2,3,4,5,6,9,10,12,19,21
	Abdominal	P	P	P	P	P	P	BMDC	Note 2,3,4,6,9,10,11,20
	Intra-operative (Note 6)	P	P	P	P	P	P	BMDC	Note 2,3,4,6,9,10
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	P	P	P	P	P	P	BMDC	Note 2,3,4,6,9,10,11
	Small Organ (Note 1)	P	P	P	P	P	P	BMDC	Note 2,3,4,5,6,9,10,11,19
	Neonatal Cephalic	P	P	P	P	P	P	BMDC	Note 2,3,4,5,9,10,11
	Adult Cephalic	P	P	P	P	P	P	BMDC	Note 2,3,4,9,10,11
	Trans-rectal	P	P	P		P	P	BMDC	Note 2,3,4,5,9,10,19
	Trans-vaginal	P	P	P		P	P	BMDC	Note 2,3,4,5,9,10,12,19, 21
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skel. (Convent.)	P	P	P		P	P	BMDC	Note 2,3,4,9,10,11
	Musculo-skel. (Superfic)	P	P	P		P	P	BMDC	Note 2,3,4,9,10,11
	Intra -vascular	P	P	P	P	P	P	BMDC	Note 2,8,9,13,14,15,16
	Other (Specify)								
Cardiac	Cardiac Adult	P	P	P	P	P	P	BMDC	Note 2,7,8,9, 13, 14,15,16,17,18,19
	Cardiac Pediatric	P	P	P	P	P	P	BMDC	Note 2,3,4,6,8,9,10,13,14,15,16
	Intra-vascular (Cardiac)	P	P	P	P	P	P	BMDC	Note 2,8,9,13,14,15,16
	Trans-esophageal (Cardiac)	P	P	P	P	P	P	BMDC	Note 2,7,9,14,17,18,19
	Intra-Cardiac	P	P	P	P	P	P	BMDC	Note 2,8,9,13,14,15,16
	Other (Specify)								
Peripheral Vessel	Peripheral vessel	P	P	P	P	P	P	BMDC	Note 2,3,4,6,9,10,11
	Other (Specify)								

N = new indication; P = previously cleared by K121699, K112596

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.  
 Note 2 Dynamic TCE Technology  
 Note 3 SieClear  
 Note 4 Advanced SieClear  
 Note 5 3-Scape 3D Imaging  
 Note 6 For example: abdominal, vascular  
 Note 7 Stress Echo Imaging  
 Note 8 Axis Edge Assisted Ejection Fraction  
 Note 9 Clarify Vascular Enhancement Technology  
 Note 10 SieScape Panoramic Imaging

Note 11 syngo Arterial Health Package (AHP)  
 Note 12 syngo Auto OB Measurements  
 Note 13 syngo Auto Left Heart (Auto LH) Technology  
 Note 14 syngo Velocity Vector Imaging Technology  
 Note 15 CartoSound Communication  
 Note 16 Intracardiac Echocardiography (ICE) Imaging  
 Note 17 syngo fourSight TEE View  
 Note 18 syngo Mitral Valve Assessment (MVA)  
 Note 19 syngo fourSight 4D imaging  
 Note 20 Contrast Agent Imaging  
 Note 21 syngo Auto follicle

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510(k) K123001

Page 2 of \_\_\_\_

## Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name:

**4C1 Curved Array Transducer for use with:  
ACUSON X700 Diagnostic Ultrasound Systems**

Intended Use:

Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
Other (Track 1 Only)	Specific (Tracks 11 & 3)	B	M	PWD	CWD	Color Doppler	Power Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal	P	P	P	P	P	P	BMDC	Note 2,3,4,5,6,9,10,12
	Abdominal	P	P	P	P	P	P	BMDC	Note 2,3,4,6,9,10, 20
	Intra-operative (Note 6)	P	P	P	P	P	P	BMDC	Note 2,3,4,6,9,10
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	Small Organ (Note 1)	P	P	P	P	P	P	BMDC	Note 2,3,4,6,9,10
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skel. (Convent.)								
	Musculo-skel. (Superfic)								
	Intra-vascular								
	Other (Specify)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intra-vascular (Cardiac)								
	Trans-esophageal (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel	P	P	P	P	P	P	BMDC	Note 2,3,4,6,9,10
	Other (Specify)								

N = new indication; P = previously cleared by K112596

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.  
 Note 2 Dynamic TCE Technology  
 Note 3 SieClear  
 Note 4 Advanced SieClear  
 Note 5 3-Scape 3D Imaging  
 Note 6 For example: abdominal, vascular  
 Note 7 Stress Echo Imaging  
 Note 8 Axis Edge Assisted Ejection Fraction  
 Note 9 Clarify Vascular Enhancement Technology  
 Note 10 SieScape Panoramic Imaging

Note 11 syngo Arterial Health Package (AHP)  
 Note 12 syngo Auto OB Measurements  
 Note 13 syngo Auto Left Heart (Auto LH) Technology  
 Note 14 syngo Velocity Vector Imaging Technology  
 Note 15 CartoSound Communication  
 Note 16 Intracardiac Echocardiography (ICE) Imaging  
 Note 17 syngo fourSight TEE View  
 Note 18 syngo Mitral Valve Assessment (MVA)  
 Note 19 syngo fourSight 4D imaging  
 Note 20 Contrast Agent Imaging  
 Note 21 syngo Auto follicle

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## Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name:

VF10-5 Linear Array Transducer for use with:

**ACUSON X700 Diagnostic Ultrasound Systems**

Intended Use:

Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
Other (Track 1 Only)	Specific (Tracks 11 & 3)	B	M	PWD	CWD	Color Doppler	Power Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal	P	P	P		P	P	BMDC	Note 2,3,4,9,10,11
	Intra-operative (Note 6)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	P	P	P		P	P	BMDC	Note 2,3,4,9,10,11
	Small Organ (Note 1)	P	P	P		P	P	BMDC	Note 2,3,4,9,10,11
	Neonatal Cephalic	P	P	P		P	P	BMDC	Note 2,3,4,9,10,11
	Adult Cephalic	P	P	P		P	P	BMDC	Note 2,3,4,9,10,11
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skel. (Convent.)	P	P	P		P	P	BMDC	Note 2,3,4,9,10,11
	Musculo-skel. (Superfic)	P	P	P		P	P	BMDC	Note 2,3,4,9,10,11
	Intra-vascular								
	Other (Specify)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intra-vascular (Cardiac)								
	Trans-esophageal (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel	P	P	P		P	P	BMDC	Note 2,3,4,9,10,11
	Other (Specify)								

N = new indication; P = previously cleared K121699

- Note 1 For example: breast, testes, thyroid, penis, prostate, etc.  
 Note 2 Dynamic TCE Technology  
 Note 3 SieClear  
 Note 4 Advanced SieClear  
 Note 5 3-Scape 3D Imaging  
 Note 6 For example: abdominal, vascular  
 Note 7 Stress Echo Imaging  
 Note 8 Axis Edge Assisted Ejection Fraction  
 Note 9 Clarify Vascular Enhancement Technology  
 Note 10 SieScape Panoramic Imaging

- Note 11 syngo Arterial Health Package (AHP)  
 Note 12 syngo Auto OB Measurements  
 Note 13 syngo Auto Left Heart (Auto LH) Technology  
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 Note 15 CartoSound Communication  
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 Note 17 syngo fourSight TEE View  
 Note 18 syngo Mitral Valve Assessment (MVA)  
 Note 19 syngo fourSight 4D imaging  
 Note 20 Contrast Agent Imaging  
 Note 21 syngo Auto follicle

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510(k) K123001

## Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name:

VF12-4 Linear Array Transducer for use with:

**ACUSON X700 Diagnostic Ultrasound Systems**

Intended Use:

Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
Other (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Power Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal	N	N	N		N	N	BMDC	Note 2,3,4,9,10,11
	Intra-operative (Note 6)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	N	N	N		N	N	BMDC	Note 2,3,4,9,10,11
	Small Organ (Note 1)	N	N	N		N	N	BMDC	Note 2,3,4,9,10,11
	Neonatal Cephalic	N	N	N		N	N	BMDC	Note 2,3,4,9,10,11
	Adult Cephalic	N	N	N		N	N	BMDC	Note 2,3,4,9,10,11
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skel. (Convent.)	N	N	N		N	N	BMDC	Note 2,3,4,9,10,11
	Musculo-skel. (Superfic)	N	N	N		N	N	BMDC	Note 2,3,4,9,10,11
	Intra-vascular								
	Other (Specify)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intra-vascular (Cardiac)								
	Trans-esophageal (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel	N	N	N		N	N	BMDC	Note 2,3,4,9,10,11
	Other (Specify)								

N = new indication; P = previously cleared

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510(k)

K123001

Page 5 of \_\_\_\_

## Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name:

**EC9-4w Convex Array Transducer for use with:  
ACUSON 7300 Diagnostic Ultrasound Systems**

Intended Use:

Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
Other (Track 1 Only)	Specific (Tracks 11 & 3)	B	M	PWD	CWD	Color Doppler	Power Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal	N	N	N		N	N	BMDC	Note 2,3,4,5,6,9,10,12, 21
	Abdominal								
	Intra-operative (Note 6)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	Small Organ (Note 1)	N	N	N		N	N	BMDC	Note 2,3,4,5,9,10
	Neonatal Cephalic	N	N	N		N	N	BMDC	Note 2,3,4,5,9,10
	Adult Cephalic								
	Trans-rectal	N	N	N		N	N	BMDC	Note 2,3,4,5,9,10
	Trans-vaginal	N	N	N		N	N	BMDC	Note 2,3,4,5,9,10,12, 21
	Trans-urethral								
	Trans-esoph. (non-Card)								
	Musculo-skel. (Convent.)								
	Musculo-skel. (Superfic)								
	Intra-vascular								
	Other (Specify)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intra-vascular (Cardiac)								
	Trans-esophageal (Cardiac)								
	Intra-Cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel								
	Other (Specify)								

N = new indication; P = previously cleared

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 Note 21 syngo Auto follicle

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off - Office of In Vitro Diagnostic Devices

510(k) K123001

Page 6 of \_\_\_\_

## Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name:

**6C2 Curved Array Transducer for use with:  
ACUSON X700 Diagnostic Ultrasound Systems**

Intended Use:

Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
Other (Track 1 Only)	Specific (Tracks 11 & 3)	B	M	PWD	CWD	Color Doppler	Power Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal	P	P	P	P	P	P	BMDC	Note 2,3,4,5,6,9,10,12
	Abdominal	P	P	P	P	P	P	BMDC	Note 2,3,4,6,9,10
	Intra-operative (Note 6)	P	P	P	P	P	P	BMDC	Note 2,3,4,6,9,10
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	P	P	P	P	P	P	BMDC	Note 2,3,4,6,9,10
	Small Organ (Note 1)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skel. (Convent.)								
	Musculo-skel. (Superfic)								
	Intra-vascular								
	Other (Specify)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric	P	P	P	P	P	P	BMDC	Note 2,3,4,6,9,10
	Intra-vascular (Cardiac)								
	Trans-esophageal (Cardiac)								
	Intra-cardiac								
Peripheral Vessel	Other (Specify)								
	Peripheral vessel	P	P	P	P	P	P	BMDC	Note 2,3,4,6,9,10
	Other (Specify)								

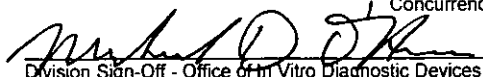
N = new indication; P = previously cleared K112596

- Note 1 For example: breast, testes, thyroid, penis, prostate, etc.  
 Note 2 Dynamic TCE Technology  
 Note 3 SieClear  
 Note 4 Advanced SieClear  
 Note 5 3-Scape 3D Imaging  
 Note 6 For example: abdominal, vascular  
 Note 7 Stress Echo Imaging  
 Note 8 Axis Edge Assisted Ejection Fraction  
 Note 9 Clarify Vascular Enhancement Technology  
 Note 10 SieScape Panoramic Imaging

- Note 11 syngo Arterial Health Package (AHP)  
 Note 12 syngo Auto OB Measurements  
 Note 13 syngo Auto Left Heart (Auto LH) Technology  
 Note 14 syngo Velocity Vector Imaging Technology  
 Note 15 CartoSound Communication  
 Note 16 Intracardiac Echocardiography (ICE) Imaging  
 Note 17 syngo fourSight TEE View  
 Note 18 syngo Mitral Valve Assessment (MVA)  
 Note 19 syngo fourSight 4D imaging  
 Note 20 Contrast Agent Imaging  
 Note 21 syngo Auto follicle

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510(k) K123001

## Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name:

**CW2 Continuous Wave Doppler Transducer for use with:  
ACUSON X700 Diagnostic Ultrasound Systems**

Intended Use:

Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
Other (Track 1 Only)	Specific (Tracks 11 & 3)	B	M	PWD	CWD	Color Doppler	Power Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal				P				
	Abdominal				P				
	Intra-operative (Note 6)				P				
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric				P				
	Small Organ (Note 1)				P				
	Neonatal Cephalic				P				
	Adult Cephalic				P				
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skel. (Convent.)								
	Musculo-skel. (Superfic)								
	Intra-vascular								
	Other (Specify)								
Cardiac	Cardiac Adult				P				
	Cardiac Pediatric				P				
	Intra-vascular (Cardiac)								
	Trans-esophageal (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel				P				
	Other (Specify)								

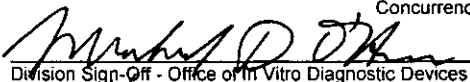
N = new indication; P = previously cleared K121699

- Note 1 For example: breast, testes, thyroid, penis, prostate, etc.  
 Note 2 Dynamic TCE Technology  
 Note 3 SieClear  
 Note 4 Advanced SieClear  
 Note 5 3-Scape 3D Imaging  
 Note 6 For example: abdominal, vascular  
 Note 7 Stress Echo Imaging  
 Note 8 Axis Edge Assisted Ejection Fraction  
 Note 9 Clarify Vascular Enhancement Technology  
 Note 10 SieScape Panoramic Imaging

- Note 11 syngo Arterial Health Package (AHP)  
 Note 12 syngo Auto OB Measurements  
 Note 13 syngo Auto Left Heart (Auto LH) Technology  
 Note 14 syngo Velocity Vector Imaging Technology  
 Note 15 CartoSound Communication  
 Note 16 Intracardiac Echocardiography (ICE) Imaging  
 Note 17 syngo fourSight TEE View  
 Note 18 syngo Mitral Valve Assessment (MVA)  
 Note 19 syngo fourSight 4D imaging  
 Note 20 Contrast Agent Imaging  
 Note 21 syngo Auto follicle

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510(k) K123001

Page 8 of \_\_\_\_

## Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **CW5 Continuous Wave Doppler Transducer for use with:  
ACUSON X700 Diagnostic Ultrasound Systems**

Intended Use: **Diagnostic imaging or fluid flow analysis of the human body as follows:**

Clinical Application		Mode of Operation							
Other (Track 1 Only)	Specific (Tracks 11 & 3)	B	M	PWD	CWD	Color Doppler	Power Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal				P				
	Abdominal				P				
	Intra-operative (Note 6)				P				
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric				P				
	Small Organ (Note 1)				P				
	Neonatal Cephalic				P				
	Adult Cephalic				P				
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skel. (Convent.)								
	Musculo-skel. (Superfic)								
	Intra-vascular								
	Other (Specify)								
Cardiac	Cardiac Adult				P				
	Cardiac Pediatric				P				
	Intra-vascular (Cardiac)								
	Trans-esophageal (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral	Peripheral vessel				P				
Vessel	Other (Specify)								

N = new indication; P = previously cleared K121699

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.  
 Note 2 Dynamic TCE Technology  
 Note 3 SieClear  
 Note 4 Advanced SieClear  
 Note 5 3-Scape 3D Imaging  
 Note 6 For example: abdominal, vascular  
 Note 7 Stress Echo Imaging  
 Note 8 Axis Edge Assisted Ejection Fraction  
 Note 9 Clarify Vascular Enhancement Technology  
 Note 10 SieScape Panoramic Imaging

Note 11 syngo Arterial Health Package (AHP)  
 Note 12 syngo Auto OB Measurements  
 Note 13 syngo Auto Left Heart (Auto LH) Technology  
 Note 14 syngo Velocity Vector Imaging Technology  
 Note 15 CartoSound Communication  
 Note 16 Intracardiac Echocardiography (ICE) Imaging  
 Note 17 syngo fourSight TEE View  
 Note 18 syngo Mitral Valve Assessment (MVA)  
 Note 19 syngo fourSight 4D imaging  
 Note 20 Contrast Agent Imaging  
 Note 21 syngo Auto follicle

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510(k) K123001

## Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name:

**AcuNav 8F Intracardiac Transducer for use with:  
ACUSON X700 Diagnostic Ultrasound Systems**

Intended Use:

Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
Other (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Power Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal								
	Intra-operative (Note 6)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	Small Organ (Note 1)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skel. (Convent.)								
	Musculo-skel. (Superfic)								
	Intra-vascular	P	P	P	P	P	P	BMDC	Note 2,8,9,13,14,16
	Other (Specify)								
Cardiac	Cardiac Adult	P	P	P	P	P	P	BMDC	Note 2,8,9,13,14,16
	Cardiac Pediatric	P	P	P	P	P	P	BMDC	Note 2,8,9,13,14,16
	Intra-vascular (Cardiac)	P	P	P	P	P	P	BMDC	Note 2,8,9,13,14,16
	Trans-esophageal (Cardiac)								
	Intra-cardiac	P	P	P	P	P	P	BMDC	Note 2,8,9,13,14,16
	Other (Specify)								
Peripheral Vessel	Peripheral vessel								
	Other (Specify)								

N = new indication; P = previously cleared K121699

- Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
- Note 2 Dynamic TCE Technology
- Note 3 SieClear
- Note 4 Advanced SieClear
- Note 5 3-Scape 3D Imaging
- Note 6 For example: abdominal, vascular
- Note 7 Stress Echo Imaging
- Note 8 Axis Edge Assisted Ejection Fraction
- Note 9 Clarify Vascular Enhancement Technology
- Note 10 SieScape Panoramic Imaging

- Note 11 syngo Arterial Health Package (AHP)
- Note 12 syngo Auto OB Measurements
- Note 13 syngo Auto Left Heart (Auto LH) Technology
- Note 14 syngo Velocity Vector Imaging Technology
- Note 15 CartoSound Communication
- Note 16 Intracardiac Echocardiography (ICE) Imaging
- Note 17 syngo fourSight TEE View
- Note 18 syngo Mitral Valve Assessment (MVA)
- Note 19 syngo fourSight 4D imaging
- Note 20 Contrast Agent Imaging
- Note 21 syngo Auto follicle

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510(k) K123001

## Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name:

**AcuNav 10F Intracardiac Transducer for use with:  
ACUSON X700 Diagnostic Ultrasound Systems**

Intended Use:

Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
Other (Track 1 Only)	Specific (Tracks 11 & 3)	B	M	PWD	CWD	Color Doppler	Power Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal								
	Intra-operative (Note 6)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	Small Organ (Note 1)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skel. (Convent.)								
	Musculo-skel. (Superfic)								
	Intra-vascular	P	P	P	P	P	P	BMDC	Note 2,8,9,13,14,16
	Other (Specify)								
Cardiac	Cardiac Adult	P	P	P	P	P	P	BMDC	Note 2,8,9,13,14,16
	Cardiac Pediatric	P	P	P	P	P	P	BMDC	Note 2,8,9,13,14,16
	Intra-vascular (Cardiac)	P	P	P	P	P	P	BMDC	Note 2,8,9,13,14,16
	Trans-esophageal (Cardiac)								
	Intra-cardiac	P	P	P	P	P	P	BMDC	Note 2,8,9,13,14,16
	Other (Specify)								
Peripheral Vessel	Peripheral vessel								
	Other (Specify)								

N = new indication; P = previously cleared K121699

- Note 1 For example: breast, testes, thyroid, penis, prostate, etc.  
 Note 2 Dynamic TCE Technology  
 Note 3 SieClear  
 Note 4 Advanced SieClear  
 Note 5 3-Scape 3D Imaging  
 Note 6 For example: abdominal, vascular  
 Note 7 Stress Echo Imaging  
 Note 8 Axis Edge Assisted Ejection Fraction  
 Note 9 Clarify Vascular Enhancement Technology  
 Note 10 SieScape Panoramic Imaging

- Note 11 syngo Arterial Health Package (AHP)  
 Note 12 syngo Auto OB Measurements  
 Note 13 syngo Auto Left Heart (Auto LH) Technology  
 Note 14 syngo Velocity Vector Imaging Technology  
 Note 15 CartoSound Communication  
 Note 16 Intracardiac Echocardiography (ICE) Imaging  
 Note 17 syngo fourSight TEE View  
 Note 18 syngo Mitral Valve Assessment (MVA)  
 Note 19 syngo fourSight 4D imaging  
 Note 20 Contrast Agent Imaging  
 Note 21 syngo Auto follicle

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510(k) K123001



## Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name:

V5Ms TEE Transducer for use with:  
ACUSON X700 Diagnostic Ultrasound Systems

Intended Use:

Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
Other (Track1 Only)	Specific (Tracks11& 3)	B	M	PWD	CWD	Color Doppler	Power Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal								
	Intra-operative (Note 6)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	Small Organ (Note 1)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skel. (Convent.)								
	Musculo-skel. (Superfic)								
	Intra-vascular								
	Other (Specify)								
Cardiac	Cardiac Adult	P	P	P	P	P	P	BMDC	Note 2,7,9,14,17,18,19
	Cardiac Pediatric								
	Intra-vascular (Cardiac)								
	Trans-esophageal (Cardiac)	P	P	P	P	P	P	BMDC	Note 2,7,9,14,17,18,19
	Intra-cardiac								
Peripheral Vessel	Other (Specify)								
	Peripheral vessel								
	Other (Specify)								

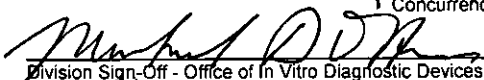
N = new indication; P = previously cleared K121699

- Note 1 For example: breast, testes, thyroid, penis, prostate, etc.  
 Note 2 Dynamic TCE Technology  
 Note 3 SieClear  
 Note 4 Advanced SieClear  
 Note 5 3-Scape 3D Imaging  
 Note 6 For example: abdominal, vascular  
 Note 7 Stress Echo Imaging  
 Note 8 Axis Edge Assisted Ejection Fraction  
 Note 9 Clarify Vascular Enhancement Technology  
 Note 10 SieScape Panoramic Imaging

- Note 11 syngo Arterial Health Package (AHP)  
 Note 12 syngo Auto OB Measurements  
 Note 13 syngo Auto Left Heart (Auto LH) Technology  
 Note 14 syngo Velocity Vector Imaging Technology  
 Note 15 CantoSound Communication  
 Note 16 Intracardiac Echocardiography (ICE) Imaging  
 Note 17 syngo fourSight TEE View  
 Note 18 syngo Mitral Valve Assessment (MVA)  
 Note 19 syngo fourSight 4D imaging  
 Note 20 Contrast Agent Imaging  
 Note 21 syngo Auto follicle

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510(k) K123001

## Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name:

**4V1c Phased Sector Array Transducer for use with:  
ACUSON X700 Diagnostic Ultrasound Systems**

Intended Use:

Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
Other (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Power Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal	P	P	P		P	P	BMDC	Note 2,9
	Abdominal	P	P	P		P	P	BMDC	Note 2,9
	Intra-operative (Note 6)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	Small Organ (Note 1)								
	Neonatal Cephalic	P	P	P	P	P	P	BMDC	Note 2,9
	Adult Cephalic	P	P	P	P	P	P	BMDC	Note 2,9
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skel. (Convent.)								
	Musculo-skel. (Superfic)								
	Intra-vascular								
	Other (Specify)								
Cardiac	Cardiac Adult	P	P	P	P	P	P	BMDC	Note 2,7,8,9, 13, 14
	Cardiac Pediatric								
	Intra-vascular (Cardiac)								
	Trans-esophageal (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel								
	Other (Specify)								

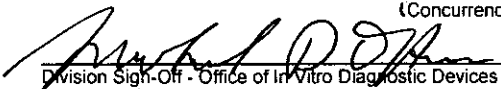
N = new indication; P = previously cleared K121699

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.  
 Note 2 Dynamic TCE Technology  
 Note 3 SieClear  
 Note 4 Advanced SieClear  
 Note 5 3-Scape 3D Imaging  
 Note 6 For example: abdominal, vascular  
 Note 7 Stress Echo Imaging  
 Note 8 Axis Edge Assisted Ejection Fraction  
 Note 9 Clarify Vascular Enhancement Technology  
 Note 10 SieScape Panoramic Imaging

Note 11 syngo Arterial Health Package (AHP)  
 Note 12 syngo Auto OB Measurements  
 Note 13 syngo Auto Left Heart (Auto LH) Technology  
 Note 14 syngo Velocity Vector Imaging Technology  
 Note 15 CartoSound Communication  
 Note 16 Intracardiac Echocardiography (ICE) Imaging  
 Note 17 syngo fourSight TEE View  
 Note 18 syngo Mitral Valve Assessment (MVA)  
 Note 19 syngo fourSight 4D imaging  
 Note 20 Contrast Agent Imaging  
 Note 21 syngo Auto follicle

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510(k) K123001

Page 13 of \_\_\_\_

## Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name:

**C7F2 Curved Array Mechanical 3D/4D Transducer for use with:  
ACUSON X700 Diagnostic Ultrasound Systems**

Intended Use:

Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
Other (Track 1 Only)	Specific (Tracks 11 & 3)	B	M	PWD	CWD	Color Doppler	Power Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal	P	P	P	P	P	P	BMDC	Note 2,3,4,5,6,9,10,12,19
	Abdominal	P	P	P	P	P	P	BMDC	Note 2,3,4,6,9,10
	Intra-operative (Note 6)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	P	P	P	P	P	P	BMDC	Note 2,3,4,6,9,10
	Small Organ (Note 1)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skel. (Convent.)								
	Musculo-skel. (Superfic)								
	Intra-vascular								
	Other (Specify)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intra-vascular (Cardiac)								
	Trans-esophageal (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel								
	Other (Specify)								

N = new indication; P = previously cleared K121699

- Note 1 For example: breast, testes, thyroid, penis, prostate, etc.  
 Note 2 Dynamic TCE Technology  
 Note 3 SieClear  
 Note 4 Advanced SieClear  
 Note 5 3-Scape 3D Imaging  
 Note 6 For example: abdominal, vascular  
 Note 7 Stress Echo Imaging  
 Note 8 Axis Edge Assisted Ejection Fraction  
 Note 9 Clarify Vascular Enhancement Technology  
 Note 10 SieScape Panoramic Imaging

- Note 11 syngo Arterial Health Package (AHP)  
 Note 12 syngo Auto OB Measurements  
 Note 13 syngo Auto Left Heart (Auto LH) Technology  
 Note 14 syngo Velocity Vector Imaging Technology  
 Note 15 CartoSound Communication  
 Note 16 Intracardiac Echocardiography (ICE) Imaging  
 Note 17 syngo fourSight TEE View  
 Note 18 syngo Mitral Valve Assessment (MVA)  
 Note 19 syngo fourSight 4D imaging  
 Note 20 Contrast Agent Imaging  
 Note 21 syngo Auto follicle

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510(k) K123001

Page 14 of \_\_\_\_

## Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name:

**EV9F4 Curved Array Mechanical 3D/4D Transducer for use with:  
ACUSON X700 Diagnostic Ultrasound Systems**

Intended Use:

Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
Other (Track 1 Only)	Specific (Tracks 11 & 3)	B	M	PWD	CWD	Color Doppler	Power Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal	P	P	P		P	P	BMDC	Note 2,3,4,5,6,9,10,12, 19,
	Abdominal								
	Intra-operative (Note 6)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	Small Organ (Note 1)								
	Neonatal Cephalic	P	P	P		P	P	BMDC	Note 2,3,4,5,9,10
	Adult Cephalic								
	Trans-rectal	P	P	P		P	P	BMDC	Note 2,3,4,5,9,10,19
	Trans-vaginal	P	P	P		P	P	BMDC	Note 2,3,4,5,9,10,12,19, 21
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skel. (Convent.)								
	Musculo-skel. (Superfic)								
	Intra-vascular								
	Other (Specify)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intra-vascular (Cardiac)								
	Trans-esophageal (Cardiac)								
	Intra-Cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel								
	Other (Specify)								

N = new indication; P = previously cleared K121699

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.  
 Note 2 Dynamic TCE Technology  
 Note 3 SieClear  
 Note 4 Advanced SieClear  
 Note 5 3-Scape 3D Imaging  
 Note 6 For example: abdominal, vascular  
 Note 7 Stress Echo Imaging  
 Note 8 Axis Edge Assisted Ejection Fraction  
 Note 9 Clarify Vascular Enhancement Technology  
 Note 10 SieScape Panoramic Imaging

Note 11 syngo Arterial Health Package (AHP)  
 Note 12 syngo Auto OB Measurements  
 Note 13 syngo Auto Left Heart (Auto LH) Technology  
 Note 14 syngo Velocity Vector Imaging Technology  
 Note 15 CartoSound Communication  
 Note 16 Intracardiac Echocardiography (ICE) Imaging  
 Note 17 syngo fourSight TEE View  
 Note 18 syngo Mitral Valve Assessment (MVA)  
 Note 19 syngo fourSight 4D imaging  
 Note 20 Contrast Agent Imaging  
 Note 21 syngo Auto follicle

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510(k) 1123001

Page 15 of \_\_\_\_

## Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name:

**SoundStar 10F Transducer for use with:  
ACUSON X700 Diagnostic Ultrasound Systems**

Intended Use:

Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
Other (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Power Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal								
	Intra-operative (Note 6)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	Small Organ (Note 1)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skel. (Convent.)								
	Musculo-skel. (Superfic)								
	Intra-vascular	P	P	P	P	P	P	BMDC	Note 2,8,9,13,14,15,16
	Other (Specify)								
Cardiac	Cardiac Adult	P	P	P	P	P	P	BMDC	Note 2,8,9,13,14,15,16
	Cardiac Pediatric	P	P	P	P	P	P	BMDC	Note 2,8,9,13,14,15,16
	Intra-vascular (Cardiac)	P	P	P	P	P	P	BMDC	Note 2,8,9,13,14,15,16
	Trans-esophageal (Cardiac)								
	Intra-cardiac	P	P	P	P	P	P	BMDC	Note 2,8,9,13,14,15,16
	Other (Specify)								
Peripheral Vessel	Peripheral vessel								
	Other (Specify)								

N = new indication; P = previously cleared K121699

- Note 1 For example: breast, testes, thyroid, penis, prostate, etc.  
 Note 2 Dynamic TCE Technology  
 Note 3 SieClear  
 Note 4 Advanced SieClear  
 Note 5 3-Scape 3D Imaging  
 Note 6 For example: abdominal, vascular  
 Note 7 Stress Echo Imaging  
 Note 8 Axis Edge Assisted Ejection Fraction  
 Note 9 Clarify Vascular Enhancement Technology  
 Note 10 SieScape Panoramic Imaging

- Note 11 syngo Arterial Health Package (AHP)  
 Note 12 syngo Auto OB Measurements  
 Note 13 syngo Auto Left Heart (Auto LH) Technology  
 Note 14 syngo Velocity Vector Imaging Technology  
 Note 15 CartoSound Communication  
 Note 16 Intracardiac Echocardiography (ICE) Imaging  
 Note 17 syngo fourSight TEE View  
 Note 18 syngo Mitral Valve Assessment (MVA)  
 Note 19 syngo fourSight 4D imaging  
 Note 20 Contrast Agent Imaging  
 Note 21 syngo Auto follicle

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510(k) K123001

Page 16 of \_\_\_\_

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name:

SoundStar eco 10F Transducer for use with:  
ACUSON X700 Diagnostic Ultrasound Systems

Intended Use:

Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
Other (Track 1 Only)	Specific (Tracks 11 & 3)	B	M	PWD	CWD	Color Doppler	Power Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal								
	Intra-operative (Note 6)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	Small Organ (Note 1)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skel. (Convent.)								
	Musculo-skel. (Superfic)								
	Intra-vascular	N	N	N	N	N	N	BMDC	Note 2,8,9,13,14,15,16
	Other (Specify)								
Cardiac	Cardiac Adult	N	N	N	N	N	N	BMDC	Note 2,8,9,13,14,15,16
	Cardiac Pediatric	N	N	N	N	N	N	BMDC	Note 2,8,9,13,14,15,16
	Intra-vascular (Cardiac)	N	N	N	N	N	N	BMDC	Note 2,8,9,13,14,15,16
	Trans-esophageal (Cardiac)								
	Intra-cardiac	N	N	N	N	N	N	BMDC	Note 2,8,9,13,14,15,16
	Other (Specify)								
Peripheral Vessel	Peripheral vessel								
	Other (Specify)								

N = new indication; P = previously cleared

- Note 1 For example: breast, testes, thyroid, penis, prostate, etc.  
 Note 2 Dynamic TCE Technology  
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